K113616

APR 2 7 2012

510(k) Summary

510 (k) Submitter/Owner	Lone Oak Medical Technologies
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Contact Person	David Comley
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Date Prepared	December 6, 2011
Trade Name	Accudxa 2 Bone Densitometer
Common Name	Bone Densitometer
Classification Name	Bone Densitometer

Predicate Devices:

Company	Device name	Product Code	510(k)
Schick Technologies	accuDEXA Bone Densitometer	KGI	K971735, K981124, K001429
Alara, Inc	Metriscan Bone Density System	KGI	K000162
Lunar Corp	PIXI	KGI	K970224

Device Description:

The Accudxa 2 Model 7200 is a Dual Energy X-ray Absorptiometer (DXA) screening device. The device is intended to calculate an index of bone mineral density in the middle finger of the non-dominant hand. By changing the high voltage on the X-ray tube, two energies are produced. Each of the two settings produces an image of the finger and each image is analyzed using various algorithms to produce a value of bone mineral density (BMD) and bone mineral content (BMC). These values are compared with a normative database, yielding a t-score and a z-score. The t-score is the number of standard deviations that the patient is above or below the mean of a reference sample of young healthy individuals, which can be used by the physician as an aid to diagnose osteoporosis or osteopenia and to estimate fracture risk. The z-score is the number of standard deviations that the patient is above or below the mean of a reference sample of individuals of the same age as the patient, which can be used by the physician as an aid to diagnose other disorders affecting bone mass.

The BMD Test interaction with the operator is through a touchscreen LCD panel and a membrane switch/indicator panel on the front of the device. BMD Test options are presented to the operator through messages on the touchscreen.

The x-ray system state and x-ray controls are presented to the operator via the membrane switch/indicator panel on the front of the device.

The Accudxa 2 is a Class II medical device and a Class II laser product.

Indications for Use:

The Accudxa 2 is a dual-energy x-ray device indicated for use in estimating the bone density of the middle finger of the non-dominant hand (BMD). This BMD value is a relative indicator of bone density elsewhere in the body. Accudxa 2 BMD estimates, t-score and z-score can be used as an aid to the physician in determining fracture risk and for monitoring changes in bone mass over time.

Nonclinical Testing:

The previous generation accuDEXA Model 7100 used a set of five calibration phantoms of known BMC and BMD value, plus a sixth Quality Control phantom supplied to customers for QC activities in the field. The calibration phantoms are intended to calibrate the device across its operating range of BMD values. The Accudxa 2 uses the same calibration phantom set to ensure that BMD readings obtained from the device are equivalent to those of the accuDEXA Model 7100.

The Accudxa 2 complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and radiation safety of medical and / or laser devices.

Technological Characteristic Comparison:

Lone Oak Medical Technologies purchased the accuDEXA Bone Densitometer design from Schick Technologies in August 2007. This design was repackaged and updated to reduce the size and weight of the unit. The same algorithms, normative database and sensor used in the Schick design (K971735, K981124, K001429) are used in the Lone Oak design. The software changes to the Schick design concern the Graphical User Interface, Operating System and communication protocol to the new hardware (touchscreen, memory, USB interface, controller board, etc.).

Conclusion:

Lone Oak Medical Technologies has demonstrated through its comparison of characteristics with the predicate devices and comparison of performance testing with the predicate devices that the Accudxa 2 Bone Densitometer is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR 27 2012

Mr. David Comley
Vice President
Lone Oak Medical Technologies
3805 Old Easton Road
DOYLESTOWN PA 18902

Re: K113616
Trade/Device Name: accudxa2 Bone Mineral Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: KGI
Dated: April 20, 2012
Received: April 23, 2012

Dear Mr. Comley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): **K113616**

Device Name: **accudxa2 Bone Mineral Densitometer**

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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